USDA

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

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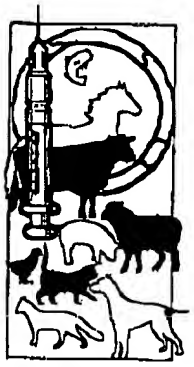

3/13/03

TO: United States Patent and Trademark Office

FROM: Rick Hill

ADDRESS:

FAX # 703-308-6916

NUMBER OF PAGES (INCLUDING THIS COVER SHEET): 3

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March 11, 2003

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
Washington DC 20231

Dear Mr. Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,275,813, filed by the Regents of the University of California, under 35 U.S.C. section 156 *et seq.* The veterinary biologic product claimed by the patent is Fel-O-Vax® FIV vaccine (Feline Immunodeficiency Virus Vaccine, Killed Virus), which was assigned VS Code No. 15A5.21 by the Center for Veterinary Biologics (CVB).

In this letter, I am amending the information regarding this product's regulatory review period that I sent to you previously in a letter dated September 24, 2002. We have reviewed the dates contained in the application and have determined the total regulatory review period for Fel-O-Vax® FIV vaccine to be 3853 days. Of this time, 2442 days occurred during the testing phase and 1411 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an Application for a U.S. Veterinary Biological Product License was submitted to the USDA for FIV vaccine: August 28, 1991.

CVB has verified the applicant's claim that an Application for a U.S. Veterinary Biological Product License for FIV vaccine was submitted to the USDA on August 28, 1991. Because the initial testing laboratory, Solvay Animal Health, held a U.S. Veterinary Biologics Establishment License pursuant to 9CFR section 102.1, they had authorization from CVB to prepare, with certain restrictions, experimental biologics and to submit biological product license applications. Subsequently, Solvay Animal Health was acquired on February 28, 1997, by American Home Products Corporation, now Wyeth Corporation. The date the first application for a U.S. veterinary biological product license was submitted to USDA is an appropriate date to recognize when "authorization to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective" [9 CFR section 124.20(a)(1)], because it marks the first official step towards licensure.

2. The date an application for a license for Fel-O-Vax® FIV vaccine was initially submitted for approval under the Virus-Serum-Toxin Act: May 4, 1998.

CVB has verified the applicant's claim that the license application for Fel-O-Vax® FIV vaccine was initially submitted on May 4, 1998.

3. The date the application was approved and a license issued: March 14, 2002.

CVB has verified the applicant's claim that Fel-O-Vax® FIV vaccine was approved and a license issued on March 14, 2002.

This determination of the regulatory review period by CVB does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if I can be of further assistance.

Sincerely,

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics